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10/521,693 09/12/2005 31846 7590 07/16/200 INTERVET INC.	Ben Adler	I-2002.011 US	8800
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		EXAMINER	
PATENT DEPARTMENT		GANGLE, BRIAN J	
PO BOX 318 MILLSBORO, DE 19966-0318		, ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

······································	Application No.	Applicant(s)			
	10/521,693	ADLER ET AL.			
Office Action Summary	Examiner	Art Unit			
	Brian J. Gangle	1645			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period variety received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tinuity will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status		•			
1) Responsive to communication(s) filed on 21 M	lay 2007.				
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3) Since this application is in condition for allowar					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.			
Disposition of Claims					
4) ☐ Claim(s) 24,29,30 and 33 is/are pending in the 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 24,29,30 and 33 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/o	wn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the drawing(s) be held in abeyance. Se tion is required if the drawing(s) is ob	ee 37 CFR 1.85(a). pjected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau * See the attached detailed Office action for a list	is have been received. Is have been received in Applications in the second in the seco	tion No red in this National Stage			
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summar Paper No(s)/Mail D 5) Notice of Informal 6) Other:	Date			

### **DETAILED ACTION**

Applicant's amendment and remarks, filed 5/21/2007, are acknowledged. Claims 24, 29-30, and 33 are amended. Claims 24, 29-30, and 33 are pending and are currently under examination.

# Specification

The objection to the disclosure, because it contains an embedded hyperlink and/or other form of browser-executable code, is withdrawn in light of applicant's amendment thereto.

The objection to the specification because of improper use of trademarks is maintained. Although applicant has amended the specification to capitalize trademark names, applicant has not included appropriate generic descriptions. It is suggested that applicant consult the MSDS sheets to determine the appropriate generic descriptions.

# Claim Objections Maintained

The objection to claims 24 and 29 because the claims contain the acronym SDS-PAGE, is withdrawn in light of applicant's amendment thereto.

### Claim Rejections Withdrawn

The rejection of claims 24, 29, and 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of applicant's amendment.

The rejection of claim 24 as being rendered vague and indefinite by the phrase "detecting *Brachyspira hyodysenteriae* antibodies," is withdrawn in light of applicant's amendment.

The rejection of claim 33 as being rendered vague and indefinite by the phrase "immunogenically effective amount," is withdrawn in light of applicant's amendment.

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The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Joens *et al.* (Infect. Immun., 54:893-896, 1986; cited in the restriction requirement filed 9/28/2006), is withdrawn. Upon further consideration, the protein that Joens *et al.* describes is not disclosed as a lipoprotein.

# Claim Objections Maintained 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic kit for detecting antibodies directed against a 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for the claim as recited, is maintained for essentially the reasons set forth in the previous office action.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

**Applicant argues:** that the current amendment obviates this rejection.

Applicant's arguments have been fully considered and deemed non-persuasive.

The examiner recognizes that applicant has amended the claim to remove the language regarding fragments, and to limit the claim to the lipoprotein having the sequence of SEQ ID NO:2. However, the issue that remains is that a protein with the sequence of SEQ ID NO:2 would only be expected to bind to antibodies directed against itself. There is no evidence (in the art or the specification) to suggest that a protein with the sequence of SEQ ID NO:2 could be used to detect antibodies directed against any other component of *Brachyspira hyodysenteriae*.

As outlined previously, the claim is drawn to a diagnostic kit for detecting antibodies to Brachyspira hyodysenteriae, comprising a Brachyspira hyodysenteriae lipoprotein having the

amino acid sequence of SEQ ID NO:2. The claimed kit must be capable of detecting any antibody directed against *Brachyspira hyodysenteriae*, including antibodies directed against components of *Brachyspira hyodysenteriae* other than the 61 kD lipoprotein.

The specification discloses a 61 kD *Brachyspira hyodysenteriae* lipoprotein with the sequence of SEQ ID NO:2. Said lipoprotein would be capable of detecting antibodies directed against itself. The specification does not disclose proteins which are capable of detecting all antibodies directed against *Brachyspira hyodysenteriae*, including antibodies directed against components of *Brachyspira hyodysenteriae* other than the 61 kD lipoprotein.

While the skill in the art of immunology is high, to date, prediction of a specific immune response for any given composition in any given animal is quite unpredictable. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al. (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al. further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Additionally, as evidenced by Greenspan et al. (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of

such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that would allow the detection of antibodies directed against *Brachyspira hyodysenteriae* can only be identified empirically. This constitutes undue experimentation. Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of antibodies to a particular epitope, the specification, as filed, does not provide enablement for the full scope of the claims.

## 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thomas *et al.* (Infect. Immun., 60:3111-

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3116, 1992; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

### Applicant argues:

- 1. That the examiner incorrectly asserts that the protein shown in the 58 (or 60) kDa band anticipates the instant invention. Applicant asserts that, with regard to Figure 1, multiple proteins are present in the 58 kDa band because Triton extraction serves to extract cell membrane proteins as well as lipoproteins.
- 2. That, with regard to Figure 3, the band shown at around 60 kDa is not an isolated protein because other proteins could be present even though they are not visualized. Therefore, Thomas does not disclose an isolated 60 kDa protein.
- 3. That, because Thomas focuses on a 16 kDa protein, rather than the claimed 60 kDa protein, there is no incentive for the skilled artisan to use that protein in a diagnostic kit for detecting swine dysentery or in an immunogenic composition pertaining to treatment of this disease.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding arguments 1-3, it is clear from Figure 1 and Figure 3, that the claimed lipoprotein is present in the bands seen in lane 1 of Figure 1 and lane 3 of Figure 3. Applicant's arguments all center around the fact that other proteins may be present in the same band. However, the assertion that many proteins can be found in this band is unfounded. It is possible that other proteins are present, however unlikely. More importantly though, the claims are drawn to an isolated protein. It is clear that Triton X-114 extraction and separation in a polyacrylamide gel are steps which isolate the protein from other cellular components.

According to MPEP 2111.01, "during examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification.)" Since applicant has not defined the term "isolated" as referring to any particular level of purity, a protein which is "isolated" from other cellular components meets this limitation of the claims. Moreover, claim 33 does not recite isolation to any degree.

Regarding argument 3, the claims are not drawn to a diagnostic kit for detecting swine dysentery or in an immunogenic composition pertaining to treatment of this disease. Claim 29 is drawn to an isolated and purified immunogenic Brachyspira hyodysenteriae lipoprotein that is 61 kD (it is noted that the specification states that 61 kD should be interpreted as 61 kD +/- 5 kD). Thomas clearly discloses a protein that meets these limitations. Claims 30 and 31 are drawn to said protein having the sequence of SEQ ID NO:2, and to an immunogenic composition comprising said protein. The protein, and a composition comprising it would necessarily be immunogenic. Moreover, unless there are multiple 61 kDa Brachyspira hyodysenteriae lipoproteins (something which applicant suggests is not true, based on the language of claim 29) the 61 kDa lipoprotein disclosed by Thomas is the same protein as disclosed by applicant, and it would inherently have the same amino acid sequence. Regarding claim 24, there is no mention of a kit to detect swine dysentery. The claim is drawn to a kit for detecting antibodies to Brachyspira hyodysenteriae. The 61 kDa lipoprotein disclosed by Thomas would be capable of detecting antibodies against itself. Furthermore, the claimed "kit" is not required to contain anything other than the lipoprotein. Therefore, packaging said lipoprotein into any form that is easy to use would be considered making a "kit" and merely calling this a kit does not render the lipoprotein patentable.

As outlined previously, the instant claims are drawn to a diagnostic kit for detecting antibodies to *Brachyspira hyodysenteriae*, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2 (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising a *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2 and an acceptable pharmaceutical carrier (claim 33).

Thomas *et al.* disclose a 60kD protein isolated from the detergent phase extraction of *Brachyspira hyodysenteriae* cell membranes (see figure 1 and page 3113, column 1, paragraph 2). Said protein was also found to incorporate a radioactive fatty acid label, showing the lipid nature of the protein (page 3113, column 2, paragraph 1). Thomas *et al.* further disclose said protein suspended in phosphate-buffered saline, which is a pharmaceutically acceptable carrier

(see page 3112, column 1, paragraph 2). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Thomas *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Thomas *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b), as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chatfield *et al.* (Infect. Immun., 56:1070-1075, 1988; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

**Applicant argues:** that Figures 5 and 6 show a band around the 66 kDa marker, but that Chatfield indicates that this band is 68 kDa and therefore cannot anticipate the claimed 61 kDa protein.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant is incorrect in their assertion that Chatfield refers to the band at 66 kDa as being a 68 kDa protein. When Chatfield mentions a 68 kDa protein, they are referring to one of the three proteins that is not cross-reactive between *T. hyodysenteriae* and *T. innocens*. This is further evidenced by the fact that there are clearly more than three protein bands present in Figure 6, and by the fact that there is a band visible just above the 66 kDa band (corresponding with a weight of 68 kDa). A lipoprotein of 66 kDa meets the molecular weight requirements set forth by applicant when describing the claimed 61 kDa lipoprotein. Moreover, claim 33 does not recite isolation to any degree.

As outlined previously, the instant claims are drawn to a diagnostic kit for detecting antibodies to *Brachyspira hyodysenteriae*, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2 (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising a *Brachyspira* 

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hyodysenteriae lipoprotein having the amino acid sequence of SEQ ID NO:2 and an acceptable pharmaceutical carrier (claim 33).

Chatfield et al. disclose a 61 kD SDS-soluble protein isolated from Treponema (now Brachyspira) hyodysenteriae (Figures 5 and 6). Due to the fact that the claimed lipoprotein is found naturally in Brachyspira hyodysenteriae, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Chatfield et al., it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Chatfield et al. anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b), as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wannemuehler *et al.* (Infect. Immun., 56:3032-3039, 1988; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

### Applicant argues:

- 1. That, Wannemuehler discloses a 66 kDa band from a Triton extraction, and that, as discussed above, membrane proteins can be extracted along with lipoproteins in a Triton extraction. Applicant therefore asserts that multiple proteins are present in the 66 kDa band shown by Wannemuehler.
- 2. That Wannemuehler focuses on proteins that are between 14 and 19 kDa. Applicant asserts that Wannemuehler teaches away from the use of proteins that are 66 kDa in a diagnostic kit or immunogenic composition pertaining to swine dysentery.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, it is clear from Figure 1, that there is a 66 kDa lipoprotein present. Applicant's argument centers around the fact that other proteins may be present in the same band. However, the claims are drawn to an isolated protein. It is clear that Triton X-114 extraction and separation in a polyacrylamide gel are steps which isolate the protein from other cellular components. According to MPEP 2111.01, "during examination, the claims must be

interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation >in light of the specification<.)" Since applicant has not defined the term "isolated" as referring to any particular level of purity, a protein which is "isolated" from other cellular components meets this limitation of the claims. Moreover, claim 33 does not recite isolation to any degree.

Regarding argument 2, the claims are not drawn to diagnostic kits or immunogenic compositions pertaining to swine dysentery. Claim 29 is drawn to an isolated and purified immunogenic Brachyspira hyodysenteriae lipoprotein that is 61 kD (it is noted that the specification states that 61 kD should be interpreted as 61 kD +/- 5 kD). Wannemuehler clearly discloses a protein that meets these limitations. Claims 30 and 31 are drawn to said protein having the sequence of SEQ ID NO:2, and to an immunogenic composition comprising said protein. The protein, and a composition comprising it would necessarily be immunogenic. Moreover, unless there are multiple 61 kDa Brachyspira hyodysenteriae lipoproteins (something which applicant suggests is not true, based on the language of claim 29) the 66 kDa lipoprotein disclosed by Wannemuehler is the same protein as disclosed by applicant, and it would inherently have the same amino acid sequence. Regarding claim 24, there is no mention of a kit to detect swine dysentery. The claim is drawn to a kit for detecting antibodies to Brachyspira hyodysenteriae. The 61 kDa lipoprotein disclosed by Wannemuehler would be capable of detecting antibodies against itself. Furthermore, the claimed "kit" is not required to contain anything other than the lipoprotein. Therefore, packaging said lipoprotein into any form that is easy to use would be considered making a "kit" and merely calling this a kit does not render the lipoprotein patentable.

As outlined previously, the instant claims are drawn to a diagnostic kit for detecting antibodies to *Brachyspira hyodysenteriae*, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2 (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising a *Brachyspira* 

hyodysenteriae lipoprotein having the amino acid sequence of SEQ ID NO:2 and an acceptable pharmaceutical carrier (claim 33).

Wannemuehler *et al.* disclose a 61 kD protein isolated from a detergent phase extraction of *Brachyspira hyodysenteriae* cell membranes (Figure 1). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Wannemuehler *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same.

Wannemuehler *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

#### Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle AU 1645

> ROBERT A. ZEMAN PRIMARY EXAMINER

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